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Date: August 19, 2003

Please Deliver To:

Name:	Examiner Ruth Smith
Art Unit:	3737
Serial No.:	09/539,015
Applicant:	Thomas R. Winston, et al.
Fax:	1-703-746-3350
Atty. Dkt. No.:	15225-41
Title:	METHOD AND APPARATUS FOR GUIDING A GUIDE WIRE
From:	Gordon F. Sieckmann

Total pages including cover page: 13

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Examiner Smith,

Please note the attached draft per our conversation.

Regards,

Gordon

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thomas R. Winston, et al.	:	Atty. Dkt. No.:15225/41
Serial No.: 09/539,015	:	Group Art Unit: 3737
Filed: March 30, 2000	:	Examiner: Ruth S. Smith
For: METHOD AND APPARATUS FOR GUIDING A GUIDE WIRE	:	

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P.O. Box 1450
Alexandria, VA 22313-1450

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In the Claims:

1. (Currently amended) Apparatus configured to guide a guide wire though body tissue, said apparatus comprising a guide wire with an optical fiber forming its distal end and with at least one interferometric guidance system coupled thereto, said interferometric guidance system for generating interference information from [the] body tissue, said interferometric system comprising a circuit for generating Doppler shift information configured to detect neovascular flow through the tissue by revealing relative changes in blood flow velocity at the guide wire distal end.

2. (Previously presented) Guide wire guiding apparatus in accordance with Claim 1 wherein said interferometric system comprises:

a low coherence illumination source for generating a first light beam;

a beam splitter for splitting the first light beam into a second light beam and a third light beam;

a first optic fiber having a first end and a second end;

a second optic fiber having a first end and a second end, said first optic fiber wrapped around a first piezo electric transducer, said second optic fiber wrapped around a second piezo electric transducer, said first optic fiber coupled to the guide wire so that said second end of said first optic fiber is adjacent said second end of said guide wire;

a fixed reflector on said second optic fiber second end;

a detecting element communicatively coupled to said first ends of said first and second optic fibers, said detecting element configured to determine interference between a light beam reflected through said first optic fiber and a light beam reflected through said second optic fiber.

3. (Previously presented) Guide wire guiding apparatus in accordance with Claim 2 wherein said low coherence illumination source comprises a laser.

4. (Previously presented) Guide wire guiding apparatus in accordance with Claim 2 wherein said low coherence illumination source comprises a superluminescent emitting diode.

5. (Previously presented) Guide wire guiding apparatus in accordance with Claim 2 wherein said circuit for detecting a Doppler shift comprises:

a broad band filter; and

a frequency-to-voltage converter coupled in series to said broad band filter, wherein said broad band filter is coupled to an output of said detecting element.

6. (Previously presented) Guide wire guiding apparatus in accordance with Claim 5, said circuit for detecting a Doppler shift further comprising an FM detector, said FM detector coupled in series to an output of said broad band filter, and to an input of said frequency-to-voltage converter.

7. (Previously presented) Guide wire guiding apparatus in accordance with Claim 1 wherein said first optic fiber second end is polished flat.

8. (Previously presented) Guide wire guiding apparatus in accordance with Claim 1 wherein said first optic fiber second end is polished at an angle of about 8 degrees relative to a cross-sectional plane orthonormal to a long axis of said first optic fiber.

9. (Previously presented) Guide wire guiding apparatus in accordance with Claim 1 wherein said second optic fiber second end is polished flat.

10. (Previously presented) Guide wire guiding apparatus in accordance with Claim 1 wherein said second optic fiber second end is polished at an angle of about 8 degrees relative to a cross-sectional plane orthonormal to a long axis of said first optic fiber.

11. (Previously presented) Guide wire guiding apparatus in accordance with Claim 1 further comprising a visual graphic display coupled to said interferometric system, said visual graphic display configured to display the interferometric information and the Doppler shift information.

12. (Currently amended) Apparatus for detecting neovascular flow through an obstruction in a blood vessel, said apparatus comprising <u>a guide wire with an optical fiber forming its distal end with at least one interferometric apparatus coupled thereto,</u>

a broad band filter coupled to an output of an interferometric apparatus, said interferometric apparatus generating interferometric peaks of varying frequencies; and

a frequency-to-voltage converter coupled in series to said broad band filter.

13. (Previously presented) Apparatus in accordance with Claim 12 further comprising an FM detector coupled to an output of said broad band filter and providing an input to said frequency-to-voltage converter.

14. (Currently amended) A method to determine neovascular flow through tissue in a vessel, said method comprising using an apparatus configured to guide a guide wire through body tissue, said apparatus comprising a guide wire with an optical fiber forming its distal end and with at least one interferometric guidance system coupled thereto, said method comprising using said interferometric system to examine the vessel and comprising performing a Doppler shift analysis on frequencies of interference peaks generated by the interferometric system examining the vessel to determine the velocity of blood.

15. (Previously presented) A method in accordance with Claim 14 wherein performing the Doppler shift analysis includes the steps of:

applying a known amplitude-modulated voltage signal to a first PZT and a second PZT to produce a first known component of a Doppler frequency shift in the frequencies of interference peaks;

measuring an actual Doppler frequency shift in the interference peaks;

subtracting the first known component of the Doppler frequency shift from the actual Doppler frequency shift to determine a second component of the actual Doppler frequency shift, wherein the second component reveals the presence of neovascular channels in the vessel.

16. (Previously presented) A method in accordance with Claim 15 wherein subtracting the first known component from the actual Doppler frequency shift to determine a second known component comprises the step of determining whether the second component has an increase in magnitude.

17. (Previously presented) A method in accordance with Claim 14 wherein said method comprises generating a Doppler shift analysis comprising comparing actual shift to predicted shift of the path length change velocity whereby the velocity path component is constant and the observed variance is from a velocity change of the sample component.

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REMARKS

Claims 1-18 are pending in the application. Claims 1-18 stand rejected as described below. Also enclosed herewith is a Submission of Marked Up Claims in accordance with 37 C.F.R. § 1.121(c)(1)(ii).

Claim 1 has been amended to additionally recite that Applicants guide wire has an optical fiber forming its distal end. No new matter is presented by this amending in that support for this amending is provided at page 3, lines 7-8 of the specification. Claim 12 has been amended to additionally recite that Applicants guide wire has an optical fiber forming its distal end. No new matter is presented by this amending in that support is provided in the specification at page 3, line 7-8. Claim 14 has been amended to recite that Applicants method uses an apparatus configured to guide a guide wire through body tissue, the apparatus comprising a guide wire with an optical fiber forming its distal end. No new matter is presented by this amending in that support is provided at page 3, line 7-8 of the specification.

Illustratively, applicants independent claim 1 reads: Apparatus configured to guide a guide wire though body tissue, said apparatus comprising a guide wire with an optical fiber forming its distal end and with at least one interferometric guidance system coupled thereto, said interferometric guidance system for generating interference information from the body tissue, said interferometric system comprising a circuit for generating Doppler shift information configured to detect neovascular flow through the tissue by revealing relative changes in blood flow velocity at the guide wire distal end.

Claims 1-4 and 7-11 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Tearney et al. This rejection is respectfully traversed along with the Examiner's reasoning.

Tearney et al. is an imaging system as whereas the claimed invention is an apparatus configured for guiding a guide wire wherein at least one interferometric guidance system is coupled to a guide wire with an optical fiber forming its distal end. (emphasis added). Applicants submit that Tearney et al. does not teach or suggest applicants' guidance apparatus, but rather Tearney et al. discloses an apparatus for imaging. Applicants' apparatus is patentably distinct over Tearney et al. Tearney et al fails to teach or suggest a system for guiding a guide wire with an optical fiber forming its distal end having an interferometric system comprising a circuit for generating Doppler shift information configured to detect neovascular flow through the tissue. More particularly applicant points out that Applicant's Claim 1 has been amended to additionally recite applicants guide wire with an optical fiber forming its distal end. This claimed feature is not taught or suggested in Tearney et al.

Thus, the rejection over Tearney et al. is overcome and should be withdrawn. While Tearney et al. mentions imaging, applicants submit that Tearney et al. fails to teach or suggest a guidance system claimed by applicants.

Claims 14, 18 stand rejected under 35 USC 102(e) as being anticipated by Izatt et al. This rejection is traversed in its entirety.

Izatt et al. discloses a method for generating a velocity-indicating, tomographic image of a sample in an optical coherence tomography system includes the steps of (a) acquiring cross-correlation data from the interferometer; (b) generating a grayscale image from the cross-correlation data indicative of a depth-dependent positions of scatterers in the sample; (c) processing the cross-correlation data to produce a velocity value and location of a moving scatterer in the sample; (d) assigning a color to the velocity value; and (f) merging the color into

the grayscale image, at a point in the grayscale image indicative of the moving scatterer's location, to produce a velocity-indicating, tomographic image.

Independent Claim 14 recites: A method to determine neovascular flow through tissue in a vessel, said method comprising using an apparatus configured to guide a guide wire through body tissue, said apparatus comprising a guide wire with an optical fiber forming its distal end and with at least one interferometric guidance system coupled thereto, said method comprising using said interferometric system to examine the vessel and comprising performing a Doppler shift analysis on frequencies of interference peaks generated by the interferometric system examining the vessel to determine the velocity of blood.

Izatt et al. fails to teach or suggest Applicants claimed invention in that Izatt et al. fails to disclose Applicants claimed method: A method to determine neovascular flow through tissue in a vessel, said method comprising using an apparatus configured to guide a guide wire through body tissue, said apparatus comprising a guide wire with an optical fiber forming its distal end and with at least one interferometric guidance system coupled thereto, said method comprising using said interferometric system to examine the vessel and comprising performing a Doppler shift analysis on frequencies of interference peaks generated by the interferometric system examining the vessel to determine the velocity of blood. More specifically Izatt et al. fails to teach and suggest Applicants' guide wire having an optical fiber forming its distal end. Moreover even if Izatt et al. were somehow modified applicants' claimed invention would not result in that applicants claimed feature of a guide wire with an optical fiber forming its distal end is not taught nor suggested by Izatt et al. Accordingly, independent Claim 14 is patentable over Izatt et al.

Claims 15-18 depend directly or indirectly from Claim 14. When the recitations of Claims 15-18 are considered in combination with the recitations of Claim 14, Applicants submit that Claim 15-18 are likewise patentable over Izatt et al.

Claims 5, 6, 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tearney et al. in view of Peterson et al. This rejection is respectfully traversed in its entirety along with its reasoning.

Applicants claimed invention is patentably distinct over Tearney et al. as Claim 1 has been shown to be patentable over Tearney et al. Claim 6 is dependent on Claim 5 which in turn is dependent on Claim 2 which in turn is dependent on Claim 1. When the recitations of dependent Claims 5 and 6 are considered in combination with the recitation of Claim 2 and in

turn with the recitation independent Claim 1, it is clear that dependent Claims 5-6 are likewise patentable over Tearney et al.

Independent Claim 12 recites an apparatus for detecting neovascular flow through an obstruction in a blood vessel, said apparatus comprising a guide wire with an optical fiber forming its distal end with at least one interferometric apparatus coupled thereto, a broad band filter coupled to an output of an interferometric apparatus, said interferometric apparatus generating interferometric peaks of varying frequencies; and a frequency-to-voltage converter coupled in series to said broad band filter. Thus independent Claim 12 is patentable over Tearney et al. Claim 13 depends on Claim 12. When the recitation of Claim 13 is combined with the recitation of Claim 12, it is clear that Claim 13 is likewise patentable.

There is nothing in Tearney et al. which, teaches or suggests the claimed invention or provides any motivation to somehow or in some way to change or modify Tearney et al. There is no suggestion in Tearney et al. to change, modify, what to change or if Tearney et al. were somehow changed for some reason that any resulting beneficial embodiment would occur. Moreover even if Tearney et al were modified for some unknown reason applicants claimed invention would not result. Moreover even if Tearney et al. were somehow modified applicants' claimed invention would not result in that applicants claimed feature of a guide wire with an optical fiber forming its distal end is not taught nor suggested by Izatt et al.

Peterson et al. (U.S. Patent No. 5,549,114) discloses an apparatus for performing Doppler blood flow studies wherein processing circuitry includes a frequency-to-voltage converter. However, Peterson et al. does not teach or suggest applicants' claimed invention in particular applicants' apparatus comprising a guide wire with an optical fiber forming its distal end and

configured to detect neovascular flow in tissue. Thus the claimed invention is patentably distinct over Peterson et al. as the above discussion shows.

There is nothing in Peterson et al. which describes the claimed invention in particular Applicants apparatus having a guide wire having an optical fiber as its distal end as called for in independent Claim 1 and independent Claim 12. Thus Claim 1 and Claim 12 are patentable over Peterson et al. Claims 5-6 are ultimately dependent on Claim 1. When the recitations of dependent Claims 5 and 6 are considered in combination with the recitation of Claim 2 and ultimately independent Claim 1, it is clear that dependent Claims 5-6 are likewise patentable over Peterson et al. Accordingly Claims 5-6 are patentable over Peterson et al. Claim 13 depends on Claim 12. When the recitation of dependent Claim 13 is taken into consideration with the recitation of independent Claim 12 it is clear that dependent Claim 13 is likewise patentable over Peterson et al. Moreover even if Peterson et al.. were somehow modified applicants' claimed invention would not result in that applicants claimed feature of a guide wire with an optical fiber forming its distal end is not taught nor suggested by Peterson et al.

The Examiner has somehow combined Tearney et al. with Peterson et al. This combination is not permissible. There is nothing in either Tearney et al. or Peterson et al., which would motivate or provide a reason (nor has the Examiner provided a sustainable reason) for somehow combining these two patents. Thus, the Examiner's combination cannot be sustained and should be withdrawn.

Claims 15-17 stand rejected under 35 USC 103(a) over Izatt et al in view of Swanson ct al. This rejection is respectively traversed.

Applicants have previously shown that Applicants independent Claim 14 is patentable over Izatt et al. Claims 15-17 depend on Claim 14. When the recitations of Claims 15-17 are considered with the recitations of Claim 1, Applicants submit that dependent Claims 15-17 are likewise patentable over Izatt et al.

Swanson et al. discloses a method of imaging and scanning and obtaining information. In contrast Applicants' invention is a guidance apparatus (emphasis added). Further applicants' claimed invention is configured to guide a guide wire having an optical fiber forming its distal end and is configured to detect neovascular flow in tissue and the velocity of blood, elements which are absent in Swanson et al. (emphasis added).

Further, Swanson et al. describes a method to compensate for varying Doppler shift induced by the method that is used to change the optical path length in their device. In the previous paragraph to the citing (look at column 9, line 1), they describe a sinusoidal motion of mirror 32. The Doppler shift is directly proportional to a change in velocity (2V/lambda) and since the motion is sinusoidal, the velocity varies as a sine function. What is being described in Swanson et al. is a method to adjust the demodulator component to compensate for this varying Doppler shift caused by the sinusoidal velocity component. Applicant wishes to emphasize that the instant application provides a method to measure the velocity component of the sample, not to compensate for a varying velocity component in the reference. (The present invention uses linear changes in the path length so that the velocity component of path length change is constant and thus the observed variance is from the velocity change of the sample component.) Thus the claimed invention is patentable over Swanson.

The Examiner has somehow combined Izatt et al. with Swanson et al. This combination is not permissible. There is nothing in either Izatt et al. or Swanson et al. which would motivate or somehow provide a reason (nor has the Examiner provided a sustainable reason) for somehow combined the teaching of Izatt et al and Swanson et al.. Thus the Examiners combination cannot be sustained and must be withdrawn as that combination is improper. Applicants respectfully submit that it would not be obvious to one skilled in the art to combine Izzat et al with Swanson et al. because there is no motivation to combine Izatt et al. with Swanson et al. As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d (Bd. Pat. App. & Inter. 1993) MPEP 2143.01. Rather there must be some suggestions, outside of applicants' disclosure in the art to combine such references. See in re Vaeck, 20 U.S.P.Q. 2d `1435 (Fed. Ct. 1991). Applicants submit that the office action fails to provide any prior art references that suggest adding together elements of the instant claims. Thus the combination of Izatt et al. with Swanson et al. is overcome and should be withdrawn.

Additionally, the impermissible combination of Izatt et al. with Swanson et al. fails to teach and suggest the claimed invention in that applicants' apparatus is a guidance apparatus comprising a guide wire with an optical fiber forming its distal end and configured to detect neovascular flow. In fact none of the cited references either alone or in combinations cited by the Examiner teach or suggest applicants' claimed invention specifically that applicants apparatus is a guidance apparatus in that it has at least one interferometric guidance system coupled to a guide wire having an optical fiber forming its distal end. Thus, this rejection is overcome and should be withdrawn. Moreover none of the cited combinations of references put

forth by the Examiner result in a guide wire having an optical fiber forming its distal end as called for in applicants' claims.

The patentability of each dependent claim on its own merits is respectfully requested since each dependent claim is also deemed to define an additional aspect of the invention requiring consideration or reconsideration, as the case may be. All rejections have been traversed and overcome and are requested to be withdrawn.

All pending claims are patentable for at least the reasons put forth by applicants above. The elements called for in the pending claims are not taught or suggested in the references asserted by the Examiner and thus all the independent and dependent claims are patentable.

In view of the foregoing remarks, all claims now active in this application are believed to be in condition for allowance. Reconsideration is requested along with early passage to issue. Favorable action and allowance are respectfully solicited. Kindly enter this amendment into the record of this application.

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Regards,

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